CLAIMS

What is claimed is:

1. (Currently amended) A collection vessel for collecting and transferring a body fluid specimen comprising: a hollow body having a first and a second end; a first seal at said first end; a plunger disposed within said hollow body between said first end and said second end; said plunger providing a second seal; a plunger lock coupled to said plunger; said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated; said plunger lock further configured to release said plunger, thereby allowing said plunger to move toward said first seal within said hollow body [;] .

2. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, further comprising: an airtight junction that interrupts said hollow body forming a first section and a second section; said first section having said first seal; said second section having said plunger and said plunger lock; said airtight junction configured to allow for separation of said first and said second section and coupling of a transfer needle to said second section.

3. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said hollow body has the shape of a hollow cylinder.

4. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said plunger lock comprises a threaded shaft and said plunger comprises a threaded receiver.

5. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said plunger lock breaks away from said plunger, thereby allowing said plunger to move towards said first seal within said hollow body.

6. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said plunger lock remains at least in part with said plunger as it moves toward said first seal within said hollow body.

7. (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, further comprising an additive within said collection vessel.

8 . (Original) A collection vessel for collecting and transferring a body fluid specimen according to claim 1, wherein said collection vessel is sterilized and packaged to maintain sterility.

9. (Original) A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of: providing a fluid collection needle having a first end and a second end; providing a sterile evacuated

specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated; providing a device for collecting a second body fluid specimen comprising a sterile hollow body having an open end, a sterile seal at said open end of said device for collecting a second body fluid specimen, said sterile seal of said device for collecting a second body fluid specimen configured wherein said sterile seal of said device for collecting a second body fluid specimen is maintained at said open end of said device for collecting a second body fluid specimen when at least a portion of said sterile hollow body is at least partially evacuated;

providing an antiseptic; preparing a site on a patient's skin for puncture using said antiseptic; piercing said site using said first end of said fluid collection needle;

at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle such that piercing through said sterile seal of said sterile evacuated specimen tube does not contaminate said second end of said fluid collection needle; at least partially filling said device for collecting said second body fluid specimen with said second body fluid specimen having fewer living contaminants than said first body fluid specimen by piercing through said sterile seal of said device for collecting a second body fluid specimen using said second end of said fluid collection needle, such that piercing through said sterile seal of said device for

collecting a second body fluid specimen does not contaminate said second end of said fluid collection needle and; selecting said second body fluid specimen for use in a diagnostic test to detect the presence of organisms in said second body fluid specimen.

10. (Original) A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting a second body fluid specimen is an evacuated culture vessel further comprising a liquid media contained within said sterile hollow body of said device for collecting a second body fluid specimen.

11. (Original) A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting a second body fluid specimen is an evacuated specimen tube further comprising an additive of sodium polyanethole sulfonate within said sterile hollow body of said device for collecting a second body fluid specimen.

12. (Original) A method for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen according to claim 9, wherein said device for collecting a second body fluid specimen is a collection vessel further

comprising: said sterile hollow body of said device for collecting a second body fluid specimen having a second end; a plunger disposed within said sterile hollow body of said device for collecting a second body fluid specimen between said open end of said device for collecting a second body fluid specimen and said second end;

said plunger sealing said sterile hollow body of said device for collecting a second body fluid specimen; a plunger lock coupled to said plunger; said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said sterile hollow body of said device for collecting a second body fluid specimen between said sterile seal of said device for collecting a second body fluid specimen and said plunger is at least partially evacuated; said plunger lock further configured to release said plunger, thereby allowing said plunger to move toward said sterile seal of said device for collecting a second body fluid specimen within said sterile hollow body of said device for collecting a second body fluid specimen.

13. (Original) A method for collecting a first body fluid specimen and second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:

providing a fluid collection needle having a first end and a second end and a tube between said first end and said second end; providing a sterile evacuated specimen tube comprising a hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is at said open end of said sterile evacuated specimen tube and said hollow body of said sterile

evacuated specimen tube is at least partially evacuated, and configured wherein said sterile evacuated specimen tube is sterilized and packaged to maintain sterility;

providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

providing an antiseptic; preparing a site on a patient's skin for puncture using said antiseptic; piercing said site on a patient's skin using said first end of said fluid collection needle; at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle; at least partially filling said evacuated culture vessel with said second body fluid specimen by piercing through said sterile seal of said evacuated culture vessel with said second end of said fluid collection needle; using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

14. (Original) A method for collecting a first body fluid specimen and second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:

providing a fluid collection needle having a first and a second end and a tube between said first end and said second end; providing a first sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said first sterile evacuated specimen tube, said sterile seal of said first sterile evacuated

specimen tube configured wherein said sterile seal of said first sterile evacuated specimen tube is maintained at said open end of said first sterile evacuated specimen tube when at least a portion of said sterile hollow body of said first sterile evacuated specimen tube is at least partially evacuated; providing a second sterile evacuated specimen tube comprising a sterile hollow body having ~~a~~ an open end, a sterile seal of said second sterile evacuated specimen tube at said open end, an additive of sodium polyanetholesulfonate within said sterile hollow body of said second sterile evacuated specimen tube, said sterile seal of said second sterile evacuated specimen tube configured wherein said sterile seal of said second sterile evacuated specimen tube is maintained at said open end of said second sterile evacuated specimen tube when at least a portion of said sterile hollow body of said second sterile evacuated specimen tube is at least partially evacuated; providing an antiseptic; providing a transfer device comprising a syringe having a hollow body and a plunger, and a transfer needle, said syringe and said transfer needle configured wherein pulling back on said plunger allows a movement of fluid into said syringe through said transfer needle; providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated;

preparing a site on a patient's skin for puncture using said antiseptic; piercing said site on a patient's skin using said first end of said fluid collection needle; at least partially filling said first sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said first sterile evacuated specimen tube using said second

end of said fluid collection needle, such that said second end of said fluid collection vessel is not contaminated by said sterile seal of said first sterile evacuated specimen tube; at least partially filling said second sterile evacuated specimen tube with said second body fluid specimen by piercing through said sterile seal of said second sterile evacuated specimen tube using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said sterile seal of said second sterile evacuated specimen tube; transferring said second body fluid specimen to said evacuated culture vessel and; using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

15. (Original) A method for collecting a first body fluid specimen and second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen comprising the steps of:
providing a fluid collection needle comprising a cannula having a first end and a second end, providing a sterile evacuated specimen tube comprising; a sterile hollow body having a open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated; providing a sterile collection vessel for collecting and transferring a body fluid specimen comprising a hollow body having a first end and second end, a first seal at said first end, a plunger disposed within said hollow body between said first end and said second end, said plunger providing a second seal,

a plunger lock coupled to said plunger, said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated, said plunger lock further configured to release said plunger thereby allowing said plunger to move toward said first seal within said hollow body; providing an antiseptic;

providing a transfer device comprising a cannula having a first end and second end, said first end of said transfer device protected by a first needle shield, said second end of said transfer device protected by a second needle shield; providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated; preparing a site on a patient's skin for puncture using said antiseptic; piercing said site on a patient's skin using said first end of said fluid collection needle; at least partially filling said sterile evacuated specimen tube with said first body fluid specimen by piercing through said sterile seal of said sterile evacuated specimen tube using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said sterile seal of said sterile evacuated specimen tube;

at least partially filling said collection vessel with said second body fluid specimen by piercing through said first seal of said collection vessel using said second end of said fluid collection needle, such that said second end of said fluid collection needle is not contaminated by said first seal of collection vessel; configuring said plunger lock to release said plunger; piercing through said first seal of said collection vessel using said

first end of said transfer device; piercing through said sterile seal of said evacuated culture vessel, such that said second body fluid specimen flows into said evacuated culture vessel and; using said evacuated culture vessel having said second body fluid specimen for a diagnostic test to detect the presence of organisms in said second body fluid specimen.

16. (Cancelled) A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising: a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile hollow body of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is at said open end of said sterile evacuated specimen tube and a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and; a device for collecting a second body fluid specimen comprising a sterile hollow body having an open end, a sterile seal at said open end of said device for collecting a second body fluid specimen, said sterile seal configured wherein said sterile seal of said device for collecting a second body fluid specimen is maintained at said open end of said device for collecting a second body fluid specimen when at least a portion of said sterile hollow body of said device for collecting a second body fluid specimen is at least partially evacuated.

17. (Cancelled) A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising: a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and; an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated.

18. (Cancelled) A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising: a first sterile evacuated specimen tube comprising a sterile hollow body having a open end, a sterile seal at said open end of said first sterile evacuated specimen tube, said sterile seal of said first sterile evacuated specimen tube configured wherein said sterile seal of said first sterile evacuated specimen tube is maintained at said open end of said first sterile evacuated specimen tube when at least a portion of said sterile hollow body of said first sterile evacuated specimen tube is at least partially evacuated and; a second sterile evacuated specimen tube comprising a hollow body having ~~a~~ an open end, a sterile seal at

said open end of said second sterile evacuated specimen tube , an additive of sodium polyanetholesulfonate within said hollow body of said second sterile evacuated specimen tube, configured wherein said sterile seal of said second sterile evacuated specimen tube is at said open end of said second sterile evacuated specimen tube and said hollow body of said second sterile evacuated specimen tube is at least partially evacuated.

19. (Original) A kit for collecting a first body fluid specimen and a second body fluid specimen, said second body fluid specimen having a lower concentration of living contaminants than said first body fluid specimen said kit comprising: a sterile evacuated specimen tube comprising a sterile hollow body having an open end, a sterile seal at said open end, said sterile seal configured wherein said sterile seal is maintained at said open end when at least a portion of said sterile hollow body is at least partially evacuated and; a collection vessel comprising a hollow body having a first end and second end, a first seal at said first end, a plunger disposed within said hollow body between said first end and said second end, said plunger providing a second seal,

a plunger lock coupled to said plunger,

said plunger lock being configured to selectively maintain said plunger at said second end when at least a portion of said hollow body between said first seal and said second seal is at least partially evacuated, said plunger lock further configured to release said plunger thereby allowing said plunger to move toward said first seal within said body.

20. (Currently amended) A method for collecting a first blood specimen and second blood specimen, said second blood specimen having a lower concentration of living

contaminants than said first blood specimen comprising the steps of: providing a blood collection needle having a first end and a second end; providing a collection kit comprising a sterile evacuated specimen tube having a sterile hollow body having ~~a~~ an open end, a sterile seal at said open end of said sterile evacuated specimen tube, said sterile seal of said sterile evacuated specimen tube configured wherein said sterile seal of said sterile evacuated specimen tube is maintained at said open end of said sterile evacuated specimen tube when at least a portion of said sterile hollow body of said sterile evacuated specimen tube is at least partially evacuated and a collection vessel comprising a hollow body having a first end and second end, a first seal at said first end of said collection vessel, a plunger disposed within said hollow body of said collection vessel between said first end of said collection vessel and said second end of said collection vessel, said plunger providing a second seal, a plunger lock coupled to said plunger, said plunger lock being configured to selectively maintain said plunger at said second end of said collection vessel when at least a portion of said hollow body of said collection vessel between said first seal and said second seal is at least partially evacuated, said plunger lock further configured to release said plunger thereby allowing said plunger to move toward said first seal within said hollow body of said collection vessel; providing an antiseptic; providing a transfer device comprising a cannula having a first end and second end, said first end of said transfer device protected by a first needle shield, said second end of said transfer device protected by a second needle shield; providing an evacuated culture vessel comprising a hollow body having an open end, a sterile seal at said open end of said evacuated culture vessel, a liquid media within said

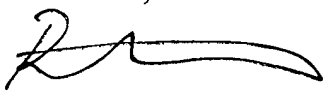
hollow body of said evacuated culture vessel, configured wherein said hollow body of said evacuated culture vessel is at least partially evacuated; opening said collection kit; preparing a site on a patient's skin for puncture using said antiseptic; piercing said site on a patient's skin using said first end of said blood collection needle; at least partially filling said sterile evacuated specimen tube with said first blood specimen by piercing through said sterile seal of said first sterile evacuated specimen tube using said second end of said blood collection needle, such that said second end of said blood collection needle is not contaminated by said sterile seal of said sterile evacuated specimen tube; at least partially filling said collection vessel with said second blood specimen by piercing through said first seal of said collection vessel using said second end of said blood collection needle, such that said second end of said fluid collection needle is not contaminated by said first seal of said collection vessel; configuring said plunger lock to release said plunger; piercing through said first seal of said collection vessel using said first end of said transfer device; piercing through said sterile seal of said evacuated culture vessel, such that said second body fluid specimen flows into said evacuated culture vessel and; using said evacuated culture vessel having said second blood specimen for a diagnostic test to detect the presence of organisms in said second blood specimen.

Discussion

To whom it may concern;

This response to the USPTO office action mailed 07/13/2004 is submitted in order to overcome objections to claims 1 and 20 of utility patent application 10/055,290 filed on 01/23/2002. In this response, claims 16,17, and 18, of application 10/055,290 are hereby cancelled. If this response is found acceptable, then I would like to proceed with utility patent issuance proceedings as soon as possible.

Thank You,



Ben Stone